EFFECTIVENESS AND ACCEPTABILITY OF FERTILITY AWARNESS-BASED GUIDELINES FOR POSPARTUM WOMEN

Report of Pilot Study

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EXECUTIVE SUMMARY

The purpose of this pilot study was to do a preliminary examination of the efficacy[1], effectiveness[2], and acceptability of new, simple fertility awareness-based (FAB) guidelines of family planning for postpartum women. The guidelines for postpartum women (PPG) counsel and teach women in the first months postpartum who wish to avoid or delay pregnancy, on which days of the cycle they should avoid unprotected intercourse to prevent pregnancy. Users of the PPG would follow simple fertility awareness-based rules to minimize their probability of pregnancy starting when they are no longer eligible to use the Lactational Amenorrhea Method (LAM) and until they are eligible to start using existing simple natural methods such as the Standard Days Method or the TwoDay method. They would avoid unprotected intercourse on varying days of their menstrual cycle, depending on where they were in the physiologically changing continuum from birth to menstrual regularity.

Some 202 women participated in this pilot study. They were counseled on how to use the Guidelines and followed periodically by study personnel, who collected information on menstrual dates, days when PPG users had intercourse (protected or unprotected), and on their experiences using the guidelines.

There were fewer pregnancies than expected: 19 pregnancies among 202 women who used the PPG for a cumulative total of 110 years. Only 3 of these pregnancies occurred in spite of users' compliance with the guidelines' rules; the other 16 pregnancies occurred in cycles when users did not follow the guidelines. This compares favorably to the estimated 50% of breastfeeding women who become pregnant in the first 12 months postpartum if they are having unprotected intercourse irrespective of when their menses return. This suggests that women who followed the Guidelines would be appropriately protected from pregnancy. However, the small sample size and relatively short period of follow up of this pilot study do not permit to calculate statistically valid efficacy rates.

Because of the rapid changes in women's reproductive physiology in the early postpartum months, no single "formula" confers appropriate protection from pregnancy. PPG users have to learn and follow different formulas (a total of three) as they move from postpartum amenorrhea to the first cycles. Study participants had no difficulty learning and using the different formulas. They and their partners found the prescribed days of use of barrier method (or abstinence) acceptable, and the vast majority complied with PPG instructions on avoidance of unprotected intercourse.

Teaching/learning different formulas requires multiple visits to or by a healthcare provider. Neither clients nor providers found this objectionable. Interestingly, health workers welcomed the PPG not only as a way to provide FP to women who prefer a

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1. Efficacy is the proportionate reduction in the probability of pregnancy during correct use of a family planning method, compared to the use of no method.

2. Effectiveness is the same as efficacy, but for *typical* use of a method.

natural method, but also a justification to follow up postpartum women, who otherwise go unattended by regular programs.

In conclusion: the Guidelines for Postpartum Women can potentially meet an important unmet need for a particularly vulnerable population. They need to be further tested to confirm these preliminary results.

ABBREVIATIONS AND ACRONYMS

APROVIME	Asociación Pro-Mujer Vivamos Mejor
CDRO	Centro de Desarrollo Rural de Occidente
FAB	Fertility Awareness-Based
FHI	Family Health International
FP	Family Planning
IRH	Institute for Reproductive Health
IUD	Inter Uterine Device
LAM	Lactation Amenorrhea Method
MOH	Ministry of Health
PPG	Postpartum Guidelines
SDM	Standard Days Method
STI	Sexually Transmitted Infection
STD	Sexually Transmitted Disease
USAID	United States Agency for International Development
WHO	World Health Organization

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I. BACKGROUND AND JUSTIFICATION

Surveys conducted in countries around the world suggest that a substantial number of women in union who use any method to prevent or delay a pregnancy state that they use a method based on periodic abstinence (Curtis and Neitzel, 1996). The majority, however, are not familiar with their fertility signs, and survey data also indicate that a significant percentage of women who are attempting to use periodic abstinence, over 60% in some populations, have incorrect knowledge about when during the menstrual cycles they are most likely to become pregnant (various reports of the Demographic and Health Surveys). This lack of knowledge and understanding can be an important source of method failure.

Another potential source of incorrect method use is the relative complexity of correctly determining fertility status using some existing FAB methods of proven effectiveness such as the Billings method and the Symptothermal method. The first cycles postpartum present additional difficulties in the use of these methods, because the normal patterns of fertility signs may not yet be established, even after potentially fertile ovulatory cycles have resumed (Brown et al., 1985). Users need to learn to recognize the symptoms of postpartum re-establishment of fertility, and distinguish between them and the usual symptoms of ovulation. This increases the complexity of the methods and can be particularly difficult for women who are new to these methods.

Special attention is needed for postpartum women to use these methods, above and beyond the methods' usual requirements (Brown et al., 1985; Labbok et al., 1991).

Recognizing the need for simple effective instructions to help women correctly identify the days each cycle when they are most likely to become pregnant if they have unprotected intercourse, the Institute for Reproductive Health, Georgetown University (IRH) developed and tested two simple FAB methods – the Standard Days Method and the TwoDay method. Efficacy studies showed that both methods are very effective when used correctly (Arévalo et al., 2001; Arévalo et al., 2003). However, a recent study of the theoretical efficacy of these methods and their usefulness for breastfeeding women found that they are not good options in the early postpartum months. The Standard Days Method, by definition, cannot be used before menstruation returns, and is not appropriate in the first postpartum cycles until cycle regularity is resumed. The TwoDay method may be very effective for postpartum women, but the identified fertile period during postpartum amenorrhea and in the first postpartum cycles can be so long that to many women it may not be acceptable (Arévalo et al., 2003).

Postpartum women are particularly vulnerable to pregnancy. For the health of the mother and infant, it is important that she not become pregnant again for at least 2.5-3 years, and recent research suggests that the ideal birth spacing interval is three to five years (Norton, 2005). Ross and Winfrey (2002) used data from 27 Demographic and Health Surveys to show that there is much unsatisfied interest in, and unmet need for, contraception in the first year postpartum. Many countries lack a system for postpartum

follow-up of women, and unlike pregnancy, there is no culture of postpartum care – new mothers, their partners, and their health providers often do not recognize the need for postpartum follow-up. Also, postpartum women often mistakenly believe that they cannot become pregnant as long as they are amenorrheic, and breastfeeding women often assume that they cannot become pregnant while they are breastfeeding. Many health providers still hold similar beliefs.

Efforts to provide a FAB method to breastfeeding women led to the development of LAM. LAM is based on three criteria. For a woman to be eligible to use LAM, she should be less than six months postpartum, amenorrheic, and fully or nearly fully breastfeeding (Labbok et al., 1994). When women are more then six months postpartum, when their menstruation returns, or when they are no longer fully breastfeeding, LAM is no longer considered as effective, and they should use another family planning method if they wish to avoid pregnancy (Labbok et al., 1997). There have been some experiences looking at the effect of breastfeeding on fertility during 9 and 12 months postpartum; but the breastfeeding practices necessary to reliably delay the return or fertility beyond 6 months are not practical everywhere. Clearly, postpartum women who are no longer eligible to use LAM or who choose not to use LAM, could benefit from simple, effective instructions to help them understand when they should avoid unprotected intercourse to prevent pregnancy.

II. THE BIOLOGICAL BASIS FOR THE PPG

Wilcox et al. (1995) show that there is a fertile window – several days in each menstrual cycle – during which a woman can, with varying degrees of likelihood, become pregnant.
The probability of clinically detected pregnancy increases progressively, from about 4% if intercourse occurs five days before ovulation, to 29% two days and 27% one day before ovulation, declining to 8% if intercourse occurs on the day of ovulation and zero thereafter.

Because of the limited viability of sperm and the very short viable lifespan of the ovum, intercourse either six or more days before ovulation or one or more days after ovulation can rarely result in pregnancy (Wilcox et al., 1998). An older study (Barrett and Marshall, 1969) and a more recent multi-center European study (1997) suggest a similar pattern.

Breastfeeding alters the normal pattern of hormonal events in the hypothalamus-hypophysis-ovary axis, resulting in suppressed ovarian activity and reduced fertility. There is much evidence that the frequency and duration of breastfeeding episodes are important in suppressing ovulation and lowering the probability of conception (World Health Organization, 1998; Rogers, 2001). Even when ovulation returns, hormonal function often remains disrupted, resulting in a still reduced probability of fertilization and implantation (Campbell and Gray, 1993). The physical symptoms associated with ovulation, such as cervical secretions, may be confusing during this period (Arévalo et al., 2003). Yet fertility eventually returns, and the probability that lactating women will become pregnant if they have unprotected intercourse increases with time. Postpartum women who do not breastfeed, or wean their infants soon after their birth, go through the same process, but their normal ovarian activity resumes sooner.

2.1 Postpartum Amenorrhea Phase ("cycle zero"):

We define *cycle zero* as the time between the birth of the child and the first postpartum menstruation (postpartum amenorrhea).[3] Studies on fertility while breastfeeding show that many, but not all, of cycles zero are either anovulatory or cannot sustain a pregnancy. Campbell and Gray (1993), for example, followed 60 breastfeeding women in the United States, and discovered that two thirds of women ovulated before their first menstruation, but 47% of those cycles had insufficient luteal-phase levels of pregnanediol. Similarly, Arévalo et al. (2003) found in an analysis of data collected by Family Health International (FHI) of 73 breastfeeding women in Britain, Canada and Australia, that about two thirds of women ovulated before their first postpartum menses, but only half of those who ovulated had a luteal phase long enough to support a pregnancy. Thus, about a third of breastfeeding women can theoretically become pregnant from unprotected intercourse on cycle zero. If they rely on resumption of bleeding as the first sign of the return of fertility, they have no warning of it. This helps

3. We use the term 'menstruation' to refer to vaginal bleeding lasting several days (although in gynecology, menstruation is sometimes restricted to mean such bleeding if it is preceded by ovulation).

explain why an estimated 5-10% of women become pregnant during postpartum menorrhea (World Health Organization, 1983).

Postpartum amenorrhea can last from five weeks (if the woman does not breastfeed), to 15 months or more (if the woman breastfeeds extensively for many months) (Arévalo et al., 2003). The end of amenorrhea is highly correlated with breastfeeding patterns, but it is impossible to predict the timing of ovulation, or even if ovulation will occur, in cycle zero. The PPG take these characteristics of cycle zero into account.

2.2 Subsequent Cycles:

Arévalo et al. (2003) examined the characteristics of postpartum cycles of 73 breastfeeding women. They used data collected by FHI in a study of the Symptothermal Method of family planning. The mean age of study participants was 29 when admitted to the study, and their average number of live births 2. Study participants contributed daily information starting 42 days postpartum, and until they had at least two 'normal' cycles (defined as cycles with adequate urinary levels of estrogens and pregnanediol glucuronide, and a luteal phase long enough to support a pregnancy[4]). Results are presented in the following table. They include all cycles in the study, regardless of duration and extent of breastfeeding.

Table 1: Characteristics of postpartum cycles

Cycle numbe	Median number of days	Range of cycle length	Ovulatory	"Normal"	Total
zero		5 weeks – 15+ mo.	app. 2/3	app. 1/3	
1	32	15 – 115 days	90.2%	57.4%	61
2	30	14 – 45 days	89.1%	63.0%	46
3	29	21 – 58 days	87.9%	69.7%	33
4	28	22 – 59 days	90.9%	81.8%	22
5+	28	22 – 35 days	97.6%	69.0 %	42

4. Ovulation in these data was defined as day of maximum urinary estrogen, measured by spectrofluorometry. A cycle was said to have adequate luteinization to support a pregnancy if more than 9.0 μmoles/24 hours of pregnanediol were measured and there was a luteal phase, as measured from the estrogen peak to the day before the next menstruation, of at least 10 days long. The cycle was considered to have an inadequate luteal phase to support a pregnancy if there were pregnanediol concentrations lower than 8.9 μmoles /24 hours or if the luteal phase was shorter than 10 days. Follicular activity with corresponding pregnanediol concentration of fewer than 4.5 μmoles /24 hours was considered to be anovulatory (Kennedy et al., 1995). This definition of ovulatory cycles was standard when these data were collected (1986-1990) (World Health Organization, 1981; Behre, 2001). We recognize that other markers of ovulation, such as serum or urinary LH concentration and urinary steroids concentration related to creatinine are the standard today. The literature suggests a high correlation between these markers (Alliende, 2002). The definition we use for an adequate luteal phase is widely used (Blackwell et al., 1998).

Not surprisingly, these figures show that with increasing cycles postpartum, the mean cycle length is progressively closer to the population mean of approximately 28 days (Vollman, 1977).

The first cycle (beginning with the first menses postpartum) is significantly longer than subsequent cycles, and the timing of ovulation in it is less predictable. After five or more menstrual bleeds postpartum, most cycles are ovulatory and most of these cycles have adequate hormonal levels and a long enough luteal phase to sustain a pregnancy. Therefore the PPG recommend different formulas for cycle zero, for cycle one and for subsequent cycles.

III. THE GUIDELINES FOR POSTPARTUM WOMEN

The Guidelines for Postpartum Women, which were the focus of this pilot study, consist of three distinct "phases". Users use a different formula in each phase to identify when they should not have unprotected intercourse if they wish to avoid pregnancy.

- "Cycle zero" – the period until the first postpartum menses;
- The cycle beginning with the first menses;
- Starting from the second postpartum menstruation, and continuing for several cycles, until the woman re-establishes cycle regularity, and is eligible to use other simple FAB methods.

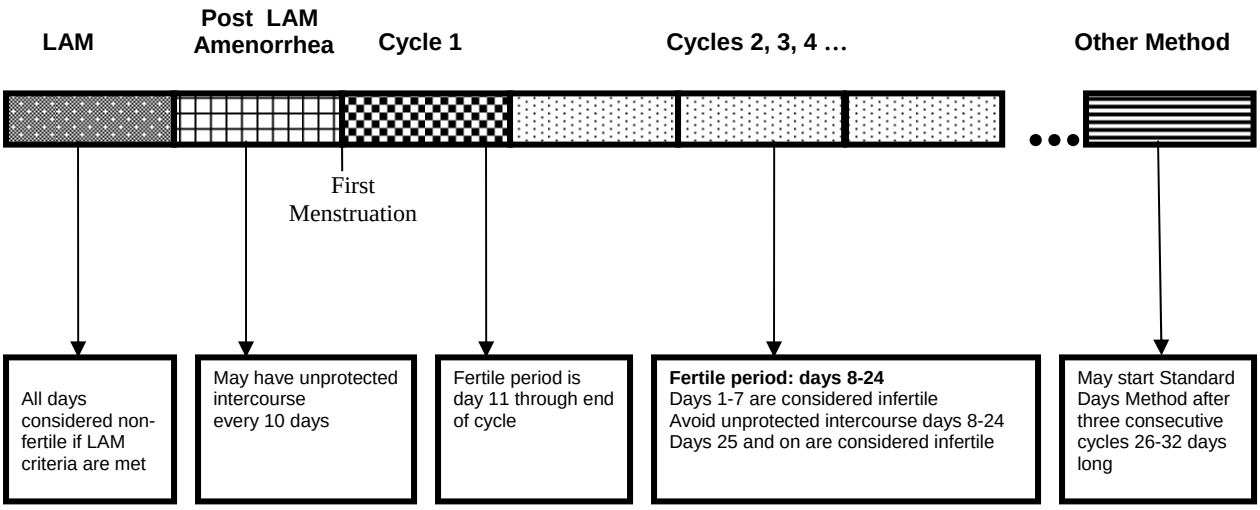
Women may begin using the PPG at any time during these three phases.

To develop the PPG we tested the theoretical efficacy of different formulae. For each phase of the method we determined what the probability of pregnancy from intercourse on a given day relative to ovulation would be if women used the guidelines correctly, using various rules to identify the fertile period. Our goal was to determine for each cycle postpartum which formula provided the best balance between efficacy in avoiding unplanned pregnancy and length of the identified fertile period. The formulae we chose provide maximum protection while minimizing the number of days of avoiding unprotected intercourse. Simplicity was also a factor: we tried as much as possible to identify formulas that would be easy to learn and use.

To determine the theoretical efficacy of the various formulae for postpartum women we analyzed the FHI data of postpartum women. Data are available on 73 post partum women in Australia, Britain, and Canada. Study participants contributed daily information starting 42 days postpartum, and until they had at least two 'normal' cycles. Daily information is available on breastfeeding and supplementation patterns and cycle characteristics such as timing of ovulation, bleeding, and cycle length.

To calculate the theoretical efficacy we assumed that on the days the formulae identify as fertile the probability of pregnancy is zero, regardless of the proximity of these days to ovulation, because the women would follow the guidelines' rules and avoid unprotected intercourse on those days. In days the formulae do not identify as fertile, the probability of pregnancy is the one suggested by Wilcox et al. (1998) for each day relative to ovulation. In anovulatory cycles and in cycles with inadequate hormonal levels and luteal phase, the probability of pregnancy was set to zero on all days of the cycle.

Figure 1: FAB Guidelines for postpartum women



Amenorrhea / Cycle zero: There is no way to predict the timing of ovulation in cycle zero, and considering as fertile the entire period, after LAM is no longer applicable, would mean many days during which the user would have to avoid unprotected intercourse. This could make the guidelines significantly less acceptable to users. We took another approach: spacing acts of intercourse. We determined that to minimize the probability of pregnancy in cycle zero after the LAM phase women would have to space days with unprotected intercourse far enough apart, that the probability that unprotected intercourse would occur on the days near ovulation would be minimal. We tested 6, 7, 8, 10, and 12-day intervals, and determined that a 10-day interval would be optimal. It would provide significant protection from pregnancy, and is also easy to remember. PPG users in cycle zero who can no longer use LAM (because they are no longer fully breastfeeding or because they are more than 6 months postpartum) or do not wish to rely on LAM would be counseled that they can have unprotected intercourse every 10 or more days. They would be instructed to mark in a calendar when they have unprotected intercourse. They should then start counting again (the next day would be day 1 of a new sequence) and avoid unprotected intercourse until the 10^{th} day or later. They would follow this pattern until they get their first postpartum menses.

Cycle one: The first cycle postpartum (which starts with the first menses) is longer than average interval cycles, and ovulation occurs later in the cycle compared to average non-postpartum cycles. But it can vary greatly in length and in the timing of ovulation, making it difficult to accurately predict the timing of ovulation.

We determined that the optimal formula that would provide sufficient protection from pregnancy yet allow the couple to have unprotected intercourse several days in the cycle is defining the fertile window as starting on day 11 of the cycle through the end of

that cycle (ending when the woman gets her second postpartum menses). PPG users in cycle one would be instructed to not have any unprotected intercourse starting on day 11 of the cycle through the end of the cycle (up to the second menstruation). Thus, the first 10 days of this first cycle are considered "safe days", during which method users may have unprotected intercourse at any time.

Subsequent cycles postpartum may still be longer than average, but as ovarian activity gradually returns to normal, cycle length and the timing of ovulation are more predictable. PPG users in these cycles would be instructed to avoid unprotected intercourse on days 8-24 of the cycle (inclusive). Days 1-7 and 25 to the end of the cycle, are considered safe.

PPG users may switch to another family planning method if they so wish as soon as they are eligible to use it. A FAB method that may be a natural progression from the PPG is the Standard Days Method, which uses a similar approach to the PPG to identify the fertile days of the cycle. The Standard Days Method identifies days 8-19 of the cycle as the fertile window. It works best for women with cycles ranging 26-32 days. PPG users who wish to switch to the Standard Days Method are eligible to switch only after they have three consecutive cycles within the 26-32 day range. This increases the probability that subsequent cycles will remain in the 26-32 day range and not return to the postpartum pattern of longer cycles.

3.1 Instructions for Guidelines users:

The following table shows the basic instructions for PPM method use in the three phases of the method.

Table 2: Basic instructions for PPM Method use

Cycle zero		Cycle 1	Cycles 2 and up
LAM	10^{th} day rule phase		
May have unprotected intercourse any day	May have unprotected intercourse every 10^{th} day. Avoid unprotected intercourse on days 1-9 of these 10-day sequences.	May have unprotected intercourse on days 1-10 of the cycle. Avoid unprotected intercourse from day 11 of the cycle until the next menstruation.	May have unprotected intercourse on days 1-7 and 25 through end of each cycle. Avoid unprotected intercourse days 7-24 of the cycle.

3.2 Theoretical efficacy of the PPM:

The following table shows the theoretical efficacy for the PPM. Theoretical results for cycle zero are conservative, because we calculate efficacy assuming unprotected intercourse exactly every 10 days, while the method instructions are to have

unprotected intercourse at least 10 days apart[5], and some users may space acts of intercourse further apart.

Table 3: Theoretical efficacy of the PPG

Cycle day	Daily probability of pregnancy		
	Cycle 0 (n=73)	Cycle 1 (n=72)	Cycles 2 and up (n=174)
Ovul. minus 5	0.001	0.002	0.003
Ovul. minus 4	0.004	0.005	0.006
Ovul. minus 3	0.003	0.003	0.002
Ovul. minus 2	0.010	0.008	0.008
Ovul. minus 1	0.009	0.004	0.011
Day of ovulation	0.003	0.001	0.004

Ovul denotes the day of Ovulation

Cycle 2 and up include cycles until the woman had three consecutive cycles that were 26-32 days long (inclusive)

These results compare very well with similar exercises performed for other simple FAB methods. The Standard Days Method and the TwoDay Method are not designed for postpartum women. Therefore a different database was used for theoretical efficacy calculations, one that did not have information of the specific day of ovulation. Peak day was used as proxy for ovulation. This resulted in an additional step in the calculation, and in a longer identified fertile period (11 days).

• The highest daily theoretical pregnancy probability for users of the Standard Days Method was 0.009, and the efficacy trial of the method showed an annual failure rate of 4.8 with correct use.

• The highest daily theoretical pregnancy probability for users of the TwoDay Method was 0.025; the efficacy trial of the method showed an annual failure rate of 3.5 with correct use.

• The highest daily theoretical probability of the PPG is 0.010 for cycle 0, is 0.008 for cycle 1, and 0.011 for cycles 2 and up. This theoretical efficacy then, suggests that the PPG is likely to provide sufficient protection from unplanned pregnancy to merit further study.

5. The analysis of theoretical efficacy for cycle zero required an additional step. We calculated efficacy 10 times, assuming a 10-day interval that begins on days 42 or 43 or 44 . . . or 51 of the cycles, and averaged the results to weigh them by the probability that the woman would begin counting her 10-day intervals on a specific day. Since available data was not specific enough to verify weather or not the women was eligible to use LAM in any part of cycle zero, the analysis assumes no LAM use.

IV. STUDY OBJECTIVES

This study was designed as the pilot phase for a larger scale study of the efficacy and effectiveness of the PPG. The primary research question of a full study would be, “What is the pregnancy rate of women who use the method as their only method of family planning, over a period of time?”

A full study would also produce other information useful in understanding the acceptability and effectiveness of the PPG and in guiding future research on the best approaches to training, client counseling, service delivery setting, and other programmatic aspects. Results of the pilot were expected to provide insights to the following questions:

- What are the continuation rates of the PPG?
- How acceptable are the resulting periods of avoiding unprotected intercourse for couples?
- How acceptable are the PPG to method providers?
- How feasible is it to deliver the PPG through a variety of programs?

4.1 Study hypotheses:

Based on the study questions, the study hypotheses posit that:

Hypothesis 1: The Guidelines will have an efficacy rate of at least 95% (i.e., no more than 5 pregnancies per 100 woman years of perfect use) and an effectiveness rate of at least 80% (i.e., no more than 20 pregnancies per 100 woman years of typical use).

Hypothesis 2: At least 80% of study participants will find the resulting period of avoiding unprotected intercourse acceptable.

Hypothesis 3: Programs and providers taking part in the study will find the method acceptable, feasible to deliver, and easy to teach.

The pilot study was expected to provide preliminary answers to these questions. However, because of the limited number of sites and participants in the pilot study, results may not be reliable. The objective of the pilot phase, therefore, was to obtain preliminary information, and to test data collection instruments, study methodology, and administrative procedures, in preparation for the full study.

V. METHODOLOGY

Clients were admitted to the study in cycle zero (both in the LAM phase and after LAM is no longer applicable), or cycle one. They were only followed for up to nine calendar months from date of admission to the study.

5.1 Study sites:

Testing the efficacy and effectiveness of the PPG was more feasible in sites were the Institute for Reproductive Health had conducted previous efficacy study, and where the mechanisms for service delivery, collecting the data, and supervising this effort were already in place. Another site requirement was the expectation that the partner organization would have the ability to recruit a sufficient number of postpartum participants in a relatively short period of time.

We carried out the pilot study in two sites: San Martin, Peru, and Totonicapan, Guatemala.

San Martin, Peru – Demand for fertility awareness-based methods has been shown to be high. The Standard Days Method is available through the Ministry of Health (MOH) network and also through some NGOs. IRH has successfully carried out research projects in the site. The PPG were offered at MOH facilities by MOH midwives and other health providers, with technical support from Instituto para la Salud Reproductiva, Peru (ISR Peru).

Totonicapan, Guatemala – Demand for fertility awareness-based methods has been shown to be high. The Standard Days Method is already available through some NGOs and through the MOH. IRH has successfully completed trials for natural methods at the site. Potential demand for a natural method for postpartum women was one of the findings of these trials. The PPG were offered through community health agents affiliated with two NGOs: CDRO (Centro de Desarrollo Rural de Occidente), and APROVIME (Associacion Pro-Mujer Vivamos Mejor).

5.2 Study population:

The target population for this study included all postpartum women, married or in union, who were interested in using a FAB method to avoid or delay pregnancy, and who were willing and able to follow the PPG instructions. For practical and ethical reasons, the study population was limited to women who met certain criteria as follows.

Ethical criteria for exclusion

The PPG pose no physical risk beyond unplanned pregnancy. As discussed above, the evidence suggests that the PPG are effective in preventing pregnancies.

However, until the PPG are proven effective in a formal efficacy trial, we cannot compare their reliability to that of family planning methods that have been proven to be effective. We recognize that pregnancy in the first months postpartum is risky, but we excluded from the study women for whom unplanned pregnancy was of particular risk, such as women diagnosed with conditions that would make a potential pregnancy a high risk, such as those who delivered through a cesarean section or experienced problems during pregnancy, labor, delivery or puerperium (e.g.: hypertension, excessive bleeding, infection, seriously abnormal labor, and others).

Furthermore, because the PPG offer no protection against sexually transmitted infections (STIs), women who were assessed by themselves or by their provider as being at risk for an STI were excluded from the pilot study.

The study population, therefore, was limited to women for whom pregnancy would not be of high risk (beyond the normal risk of pregnancy in the early postpartum period), who were not at high risk for STDs, and who chose to participate in the study after being informed of the limitations and the experimental nature of the PPG.

Criteria for inclusion

Potential participants were screened to verify that they meet the above and the following criteria:

- Age between 18 and 39 at the time of admission. These are peak years of fertility, so limiting participants to women in this age group increased the validity of study results;
- At least 2 months post-partum (to avoid confusing lochia with menstrual bleeding);
- In cycle zero (before first menses) or cycle one postpartum;
- If in cycle zero, clearly in amenorrhea;
- If in cycle one, clearly post-menstruation[6], and in first 10 days of the cycle;
- Not pregnant (if in cycle zero this was determined with a pregnancy test; if in cycle one, this was ensured by admission in the first 10 days of the cycle only);
- No use of hormonal medication since the birth of the child, so that fertility is restored at its natural pace.
- Not currently using any effective method of family planning correctly and consistently.
- Spouse agreed to woman's participation in the study. This was important because managing the fertile period involved both the woman and her partner;
- Sexually active; and
- Numeracy (of woman or spouse).

There were no restrictions regarding parity, type of marital union, and duration of union.

6. Our operational definition of menstruation was bleeding that the woman recognized as menstruation, and that was abundant (may require protection).

5.3 The sample:

For this pilot phase, information was collected on 202 women in the 2 communities. Allowing admission at two points on the postpartum period allowed us to complete the pilot test in a reasonable amount of time, despite the uncertain length of cycle zero. All women contacted by IRH's research partner institutions in the selected sites who wished to participate in the study and who met the eligibility criteria were enrolled. They were then followed for up to nine calendar months or until they have three consecutive cycles within the 26-32 day range (whichever was sooner), unless they wished to terminate their participation earlier.

As we expected, most of the women admitted in cycle zero moved on to cycle one during their participation in the study, but some stayed in amenorrhea. We also expected that most women who were admitted in cycle one would eventually have three cycles of 26-32 days during the study period.
This design allowed providers sufficient experience in utilizing the study tools and instruments, provided a large enough sample to reflect the variability of the study population, and provided information on the reliability of study instruments and the appropriateness of the Guidelines and study methodology.

5.4 Study procedures:

This section describes in detail screening, admission, follow-up, and exit procedures for the study. All data collection tools referred to are attached in the appendix. To allow for data collection women were followed monthly, more than the anticipated frequency of client-provider contact that would be required for regular delivery of the method.

Recruitment into the study

Participants were recruited into the study through community education and outreach activities, as well as through interviews with women who sought services of the local health service-delivery organizations involved in the study. Outreach activities took place in places frequented by postpartum women, such as well-baby clinics. Some women were notified of the study and method when they gave birth in a health center. Specific recruitment activities varied, depending on the characteristics of the study site.

Screening potential study participants

The method was described to all women who expressed an interest in using it and participating in the study. A Screening form (attached) was administered to all women who were still interested after receiving this preliminary information.
The form included questions related to the eligibility criteria, and allowed a full assessment of each woman' eligibility to participate in the study. Based on the information provided by the client, it was determined whether she was eligible to participate in the study.

Women who met the eligibility criteria and chose the PPG received a full description of the guidelines and the study.
They then confirmed their decision to participate in the study by written informed consent. Providers read and explained to the woman or couple a Consent form (attached). The woman was asked to sign the form. A standard Consent form, translated into the appropriate local language, was used for all clients at all sites.

Admission to the study

Women who signed the Consent form were then admitted to the study, and a Client Data form (attached) was completed. This was the only form containing identifying information about the woman. It was stored separately from all other study forms. Women were assigned a case number, which was the only identifying information that appeared on other forms. To ensure that women who entered the study were not already pregnant, a urine pregnancy test was administered to all potential participants who were in cycle zero (in the LAM phase or beyond LAM). Potential participants were only admitted to cycle one if they were on days 1-10 of their cycle (before the start of their fertile window, to ensure they were not pregnant). Also, women who were not sure of their partner's support of their use of the PPG and participation in the study were not admitted at this moment, but were asked to return when they had ascertained their partner's willingness to participate.

An Admission form (attached) was administered. This form contained questions about demographic characteristics of the women and her reproductive history. Participating women then received counseling on how to use the PPG, and were provided with the study materials. Women eligible to use LAM were counseled to continue breastfeeding fully. They were not counseled on other phases of the method until they no longer meet one or more of the LAM criteria. Women admitted to the "every-10^{th}-day" phase of cycle zero, received counseling on the 10^{th} -day rule only. Women admitted in their cycle one, received counseling on cycle one only. Women admitted to the LAM phase were asked to visit or send word to the provider as soon as they stopped breastfeeding fully or when the baby turned six months old. All women were asked to return to the provider immediately when they got their period. A schedule for follow-up was set up to follow each woman until she menstruated.

Follow-up procedures

Participants who were admitted in cycle zero (in the LAM phase or in the 10^{th} -day rule phase) were visited once a month, until they got their first postpartum menses. Similarly, in cycle one women were visited monthly until they menstruated. In cycles two and up women were visited bi-weekly, starting at one month, until they menstruated. A urine pregnancy test was administered in all these visits to ensure that they were not pregnant.

Participants were followed for nine calendar months from the date of admission or until they had three consecutive cycles that were 26-32 days long, whichever occurred

sooner, unless they got pregnant or wished to exit the study earlier for any reason. These procedures are detailed below.

The first level of data collection was administered by the clients themselves. Each woman kept a coital log on a Diary Card provided (attached).
Women were asked to avoid unprotected intercourse r on days identified by the method as fertile, but to mark in their diary cards when they did have intercourse (protected or unprotected. Women checked each day one of three options: (a) unprotected intercourse, (b) intercourse with another backup protection method, or (c) no intercourse. Requesting that women mark an option every day, even on days when they had no intercourse, increased the accuracy of the marking and the validity of results.

Follow up for cycle zero – LAM phase

The Diary Card for the LAM phase of cycle zero (see appendix) is a monthly calendar, with spaces to mark each day sexual intercourse, including use of a backup method if applicable.
A follow-up visit was scheduled for approximately once a month, for as long as the woman used LAM. The information in the Diary Card was reviewed by the client and the service provider during each follow-up visit. In addition, a Follow-Up Form (see appendix) was administered. Women who expressed a wish to get pregnant soon were dropped from the study, as were women who wished to terminate their participation in the study for any other reason.

Each follow-up visit included a urine pregnancy test. If positive, the woman was administered a Pregnancy Form (attached). Participants with negative pregnancy tests who chose to continue participating in the study continued in the LAM phase of the study, for as long as they met all three of the LAM criteria. Women were instructed to visit or send word to their provider:

- as soon as they stopped breastfeeding fully (to be counseled in the 10^{th}-day rule phase of the PPG), or
- as soon as they got their first postpartum period (to be counseled in the cycle one rule of the PPG). A Follow-Up Form was also administered during this last LAM-phase visit.

Follow up for cycle zero – 10^{th} -day rule phase

The Diary Card for the 10-day rule phase is also a monthly calendar, with spaces to mark the relevant information, including both the coital log and how the woman kept track of her days. The woman was asked to mark in her calendar every morning. Each time the woman had unprotected intercourse she marked the following day on the Diary Card as day 1 (a special place on the Card was provided to mark the counting days). The next day, she marked as day 2 and so on, marking each morning until the 10^{th} day.

She was instructed not to have intercourse on days 1-9. She could have unprotected intercourse again on any day from the 10th day on (she did not need to number days 11 or higher in her Diary Card), but only on one day. As soon as she had unprotected intercourse again, the following day was the new Day One.

A follow-up visit was scheduled for approximately once a month, for as long as the woman was amenorrheic or until she had completed nine months in the study, whichever happened sooner. The information on the diary card was reviewed by the client and the service provider during each of the follow-up visits. In addition, a Follow-Up form (see appendix) was administered.
The Follow-Up form included questions concerning method use, satisfaction, and willingness to continue in the study. Women who expressed a wish to get pregnant soon were dropped from the study, as were women who wished to terminate their participation for any other reason.

Each follow-up visit included a urine pregnancy test. If positive, the woman was administered a Pregnancy form (see appendix). Participants with negative pregnancy tests and who chose to continue participating in the study were issued the Diary Card for the next calendar month, and a date was set for the next follow-up visit, approximately a month later. Women were instructed to visit or send word to the service provider immediately if they got their period before the next scheduled follow-up visit. Once the woman had her period, a follow-up form was administered. The woman was then counseled in the use of the method for cycle one, and issued the cycle one Diary Card (see appendix).
Women who completed nine months in the study and were still in cycle zero (still in amenorrhea) were removed from the study at the end of the nine months.

Follow-up procedure for cycle one

Follow-up in cycle one was the same for participants who were admitted to the study in cycle one, and for participants who were admitted in cycle zero and had their first menses postpartum while in the study. In cycle one participants needed to mark in a different Diary Card (see appendix). This Diary Card was not a calendar. Instead it was based on the woman's menstrual cycle. The first 10 days of the cycle, when PPG users could have unprotected intercourse in cycle one without worrying about pregnancy, were shaded in a different color from the rest of the cycle. Participants also marked days of their cycle with menstrual bleeding, and had space to mark intercourse information (including use of other methods when applicable) for each day of the cycle. The cycle one Diary Card consisted of 45 days. Women whose cycle was longer than 45 days received "extension" cards.

Participants were visited once a month, and a urine pregnancy test was administered, but no follow-up form was completed until the woman got her second period postpartum, or unless a pregnancy test was positive (in which case the provider administered both the Follow-Up Form and the Pregnancy Form).

When participants received counseling on how to use the PPG in cycle one, they were instructed to visit or send word to the provider immediately when they get their period. A Follow-Up form (see appendix), similar to the one used in cycle zero, was administered during this visit. This form included questions concerning method use, satisfaction, and willingness to continue in the study. Women who expressed a wish to get pregnant during the next cycle were dropped from the study, as were women who wished to terminate their participation for any other reason. Women who chose to continue participating in the study received counseling in PPG use during cycles 2 and up, and a diary card to use in cycle two. Women who completed nine months in the study while in cycle one were removed from the study at the end of the nine months.

Follow-up for cycles 2 and up

Because PPG users in cycles two and up consider themselves fertile during days 8-24 of the cycle, users in cycle one were instructed to visit or send word to their provider as soon as they got their second postpartum period, so that they could be counseled in cycle-2 method use during the first 7 days of their second postpartum cycle. If a woman returned later than day 8 in her second cycle she was removed from the study because she may already have been pregnant.

Participants counseled in the use of PPG in cycle 2 and up got a new Diary Card (see appendix), in which days 8-24 (the fertile window) were shaded in a different color than other cycle days, to help the woman remember when she had to avoid unprotected intercourse to prevent pregnancy. The card contained spaces to mark intercourse and menstruation.

Participants were visited about a month after the beginning of the cycle; if they still have not had their period they were then visited at bi-weekly intervals until they menstruated. During these visits if the woman had not yet menstruated she was administered a urine pregnancy test; if the pregnancy test was positive a Follow-Up Form (see appendix) and a Pregnancy Form were administered. Otherwise the Follow-Up Form was administered only at the last visit for the cycle after they menstruated again (for most women, this was their only visit). The Follow-Up Form was similar to that administered in earlier phases of the study. It contained questions on method use, satisfaction, and willingness to continue in the study. Women who expressed a wish to get pregnant during the next cycle or who wished to leave the study for any other reason were removed. Women who chose to continue participating in the study were issued a new diary card, and a date was set for the next follow-up visit. This procedure continued for up to 9 calendar months from the date of admission to the study, or until the participant had three cycles that were 26-32 days long, whichever was sooner. Women who completed nine months in the study and still had not had three consecutive cycles 26-32 days long were dropped from the study at the end of nine months.

5.5 Exit procedures:

An Exit form (attached) was administered to study participants when they left the study (for reasons other than pregnancy), and identified the reason for exit. Possible exit reasons included completion of her participation in the study (either end of nine calendar months, or three consecutive cycles that are 26-32 days long), or personal reasons for wanting to leave the study or stop using the method. The Exit form included more questions about the use and acceptability of the PPG.

During the pilot study, some participants were asked to participate in focus group discussions or in-depth interviews, to obtain additional information on the use and acceptability of the method.

Women were considered lost to follow-up only after at least three attempts to find them. Providers completed a Lost-to-Follow-Up form (see appendix) when they considered a participant to be lost to follow-up.

5.6 Analysis:

Data were entered and analyzed by IRH statisticians. Since the purpose of the pilot study was to test survey instruments, study methodology and procedures, some frequencies and crosstabulations were examined to provide preliminary results on effectiveness and acceptability. Life table were calculated to estimate pregnancy rates, recognizing that results may not be statistically significant given the small sample size.

5.7 Validity of results:

Participants were contacted by providers approximately once a month during cycle zero, and at least once each cycle in subsequent cycles, for the duration of their participation in the study. Such a schedule of follow-up is neither necessary for delivery of the guidelines nor practical for most health care programs. It may also bias method effectiveness and continuation rates. However, this intensive follow-up was necessary for data collection.

Another validity issue is that of recall – participants were interviewed once a month and asked questions about the previous month. This problem was minimized by instructing participants to complete the diary card daily, and to mark something every day – not only when intercourse occurred, but also on days when it did not. Experience in previous IRH studies using similar tools show satisfactory results. For example, coital frequency reported by participants of the Standard Days Method (mean 5.5 per cycle) is very similar to that reported by users of other coitus-dependent methods in 32 countries (64 yearly, 5.3 monthly) (Arévalo et al., 2001), and by users of LAM in 10 countries (5.4 monthly) (Labbock et al., 1997).

We are aware that the results of the pilot phase with regard to efficacy of the PPG are preliminary, and cannot be generalized to the general population.

VI. ORGANIZATION

This section describes several aspects of study organization, including study responsibilities, training, and monitoring procedures.

6.1 Study responsibilities:

The study was conducted by IRH, in collaboration with local institutions and colleagues in the study sites, utilizing existing networks, facilities, logistics, and management and service delivery systems.

Site and partner institution selection criteria included:

- Potential for recruiting a sufficient number of appropriate study participants;
- Ability to follow the research protocol, including data collection, follow up, and procedures to ensure informed consent;
- Credibility with scientific and reproductive health communities; and
- Ability to train and monitor providers who provided quality services in a non-biased manner.

With the local principal investigators, IRH also selected and trained site coordinators who implemented the work plan, arranged for training of health workers and service providers, and monitored the progress of the study.

The trained health workers had a dual role: service delivery and data collection. They provided the method to clients and also administered the questionnaires. They screened potential clients to determine their eligibility to use the PPG and participate in the study; enrolled into the study women who met the criteria and wished to participate; provided counseling in use of the method to enrolled women (participants in the study); provided diary cards and counseling on their use to participants; and did follow-up visits to clients, as described above. Previous IRH experience with such dual role modality has been very successful.

Client confidentiality was a top priority for the Director of the study, the Principal Investigators, the site coordinators, and any others involved with the study. Identifying information such as name and address was kept separate from all forms except Consent and Client Data forms; forms were linked only by case number and date of birth. Only study personnel were allowed access to the files.

6.2 Training procedures:

Training of service providers (who were also interviewers) was done jointly by the site coordinator, the local principal investigator, and IRH staff. IRH trained the local principal investigators; and site coordinators were trained by the principal investigators in conjunction with IRH staff.

Topics covered by the training included male and female fertility, the use of the diary card, service delivery protocols, and the various forms used for data collection. IRH investigators closely monitored all study activities through site visits, telephone and e-mail contact, and review of all data and information coming from the field.

VII. TIMELINE

The following table shows the timeline for the study.

Table 4: Timeline for the PPM study

Organization	x	x															
Validation of materials		x															
Training			x														
Recruitment				x	x	x	x										
Follow-up					x	x	x	x	x	x	x	x	x	x	x		
Data Entry				x	x	x	x	x	x	x	x	x	x	x	x		
Data analysis																x	
Reports																	x

This time table reflects that recruitment took several months. Data entry was continuous.

VIII. FINANCING

This Pilot Study was funded in its entirety by the Institute for Reproductive Health, Georgetown University with core funds from the United States Agency for International Development (USAID).

IX. RESULTS

A total of 202 women were admitted to the pilot study, with a mean age of 25.6. They all had a baby, age 2-18 months (mean 4 months). Table 1 shows the participant profile.

Table 5: Profile of participants in the pilot study of the fertility awareness-based family planning guidelines for postpartum women (n=202)

Characteristics	Percent of participants
Study site	
Totonicapan, Guatemala	40.1
San Martin, Peru	59.9
Age at admission	
18-24	51.0
25-29	27.2
30-34	13.4
35-39	8.4
Parity	
Baby only	29.7
Baby and 1-2 older children	47.5
Baby and 2-4 older children	15.8
Baby and ≥5 older children	6.9
Education	
No formal schooling	7.4
Some primary education	37.1
Completed primary education	31.1
Completed secondary education	12.4
Some technical or university	11.9
Occupation	
No income-earning occupation	65.7
Artisan or vendoe	18.9
Blue collar job	2.0
White collar job	10.0
Services	3.5
Ever-use of family planning methods[a]	
None	45.5
Periodic Abstinence	20.8
Standard Days Method	1.5
TwoDay Method[b]	3.0
LAM	4.0
Withdrawal	10.9
Barrier Method	19.3
Pills	25.7
Injectables	21.8
IUD	5.0
Age of baby at admission	49.5
2-4 months	16.8
4-6 months	27.7
6 months-1year	5.9

≥1 year	
Breastfeeding status at admission	0.5
Not breastfeeding	2.5
1-5 times a day[c]	54.5
≥6 times a day with supplementation	42.6
≥6 times a day with no supplementation	

a Respondents indicated more than one option, so figures sum to more than 100%.
b The TwoDay Method is a fertility awareness-based family planning method based on the identification of the presence or absence or cervical secretions (reference).
c A day is 24 hours.

There was considerable variability between sites, partly because the Guatemala site was more rural than the Peru site. The educational level of participants in Guatemala was significantly lower than that of participants in Peru. While most participants in Peru could read well, only 72% of participants in Guatemala could. Also, all participants in Peru could write the numbers 1-10. In Guatemala 4.1% of participants could not. They were admitted to the study after verifying that their husbands were numerate. The education of partners also varied – some 40.7% of partners in Peru had some post-secondary education, compared to only 3.3% of partners in Guatemala.

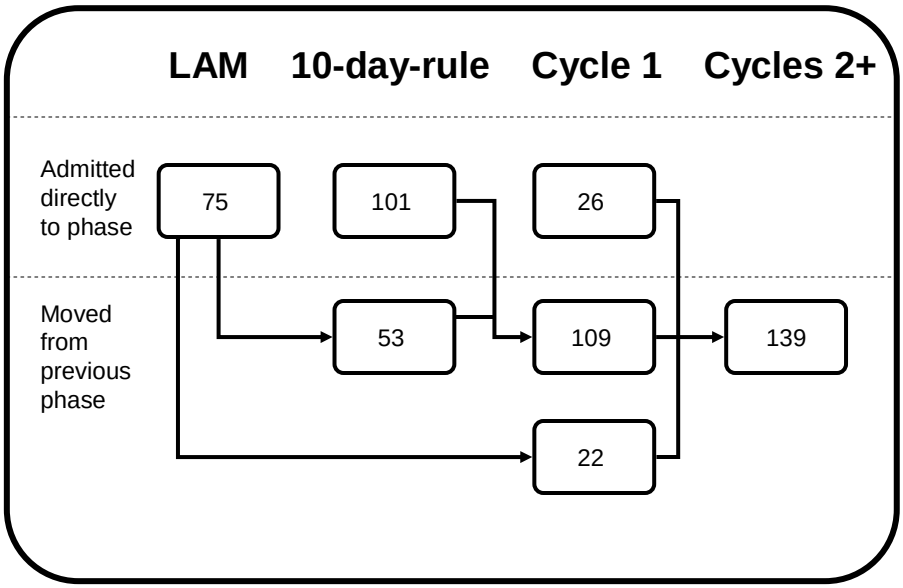
Participants in Guatemala were poorer than the Peruvians. Only 80.2% of Guatemalan participants had running water in their homes, compared to 91.4% in Guatemala; only 14% of Guatemalans used a modern stove for cooking, compared to 64.2% of Peruvians.

There was also considerable variability in previous use of family-planning method. Some 69.4% of participants in Guatemala had never used a family-planning method, and only 10.7% had ever used a hormonal method or IUD. In contrast, only 9.9% of Peruvian participants had never used a family planning method; 65.4% of them had used a hormonal method or IUD.

9.1 Progression through the *Guidelines* phases:

Some 202 women were admitted to the study. Of those, 75 were admitted to the LAM phase; 101 were still amenorrheic but were no longer eligible to use LAM and were admitted to the 10-day-rule phase; and 26 had already menstruated once postpartum, and were admitted directly to Cycle 1. The latter include four women who were actually admitted to the 10-day-rule phase, but got their period within days. Since they were not exposed to the risk of pregnancy while in the 10-day-rule phases, we considered them admitted directly to Cycle 1. Figure 1 shows the progression of participants through the different phases of the *Guidelines*.

Figure 1: Moving through the phases
Pilot study of the fertility awareness-based family planning guidelines for postpartum women (n=202)



Of the 75 women admitted to the LAM phase, 22 menstruated and moved on to Cycle 1; 53 stopped breastfeeding fully or nearly fully, or their baby turned six months old, and they moved to the 10-day-rule phase.

Overall, 154 women used the 10-day-rule phase – 101 were admitted directly to that phase, and 53 moved there from the LAM phase. Some 157 women used the *Guidelines* in Cycle 1 – 26 were admitted directly to that phase, 21 moved there form the LAM phase, and 109 moved there form the 10-day-rule phase. Some 139 women used the *Guidelines* in Cycles 2+ -- all moved there when they menstruated for the second time postpartum at the end of Cycle 1.

Cycle 0: the 10th-day-rule phase

Of the 176 women who were admitted to the study while still amenorrheic, some 135 got their first period postpartum while in the study. The mean length of postpartum amenorrhea was 282 days (median 280 days, minimum 67 days, maximum 590 days).

The focus of our examination of Cycle 0 is the 10-day rule phase, because LAM has already been extensively researched, and was not the focus of this study. A total of 154 women used the 10-day-rule *Guidelines* – 101 were admitted directly to this phase and 53 moved there from the LAM phase. The *Guideline* instructed users of the 10-day-rule to only have unprotected intercourse every 10 or more days. This does not mean that they had to have unprotected intercourse exactly every 10 days. They could postpone having unprotected intercourse as long as they wished. But when they had unprotected intercourse they started counting to 10 again. If they wished to have intercourse before the 10-day count was over, they were instructed to use a barrier method. If a woman

had unprotected intercourse before the 10 days had passed, she started counting from one the next day.

Some 43 women left the study before they got their first period postpartum – either the 9-month study period ended, or they chose to leave for another reason. Given that a woman can only ovulate once prior to her first menses, we can therefore say for sure that 111 women were exposed to the risk of pregnancy while in this phase of the *Guidelines*. Of these only 2 became pregnant – one in Guatemala and one in Peru; one correct method use (waiting at least 10 days between unprotected intercourse), and one incorrect use (had unprotected intercourse two consecutive days).

About a third of women ovulate before their first menses and have hormone levels that can support pregnancy[1] (Campbell, 1993), and studies show that up to 13% of breastfeeding women become pregnant during postpartum amenorrhea, especially in societies where intercourse during lactation is not taboo (Campbell 1993, Badraui). Since most participants in our study no longer had the protective effect of intense breastfeeding, we expect that this proportion could have been substantially higher – in their last follow-up interview while in the 10-day-rule phase only 20.8% of participants were breastfeeding three or more times per 24 hours. Our findings suggest, then, that the 10-day-rule phase of the *Guidelines* may offer a significant protection from pregnancy.

Correct use of the 10-day-rule means not having unprotected intercourse more often then every 10 days. We divided the period women used the 10-day-rule into 10-day sequences. Each 10-day sequence began the day after the woman had unprotected intercourse, and ended the day she again had unprotected intercourse. Some sequences were not complete because the woman got her period or left the study before the end of the sequence. We exclude these sequences from the following analysis. Overall participants contributed information for 1641 completed sequences – sequences that ended with unprotected intercourse -- ranging in length from 1 day (when the woman had unprotected intercourse on two consecutive days) to 48 days. Individual women contributed between 1 and 28 sequences (mean 10.9 sequences, median 10 sequences). The mean sequence length was 11.1 days, and the median and mode 10 days.

Only 3.2% of sequences were shorter then 10 days (incorrect use of the guidelines). These shorter sequences were contributed by 15.9% of participants, suggesting that even participants who broke the rules were not chronic rule breakers. They followed the *Guidelines* for the most part, but some occasionally had a shorter sequence. Only 6.6% of participants had a short sequence more then once during their participation in the study.
Most participants preferred to abstain from intercourse on the days they were instructed not to have unprotected intercourse. Participants reported protected intercourse in only 15.7% of completed sequences, contributed by 36.4% of participants.

It is interesting to note a difference in the use of the 10-day-rule *Guidelines* between the two countries. Table 2 shows various statistics that demonstrate this. Participants in Peru had more variability in the length of their sequences and more sequences shorter then 10 days contributed by a higher proportion of women. They also tended to have protected intercourse more frequently then the Guatemalans. We can speculate that these findings reflect differences in prevalence and ultimate application of beliefs of individual invincibility, fatalism, risk taking, the protective role of amenorrhea, and the protective role of having unprotected sex just once in the fertile days.

Table 6: Correct use of the 10-day rule phase by country (n=1641 phases; 154 women)

	Guatemala	Peru
Mean length of sequence	11.3	10.7
% of sequences that were exactly 10 days long	66.9%	59.9%
% of sequences shorter then 10 days	0.3%	9.7%
% women who had 1 sequence shorter then 10 days	4.0%	18.0%
% women who had more than 1 sequence shorter than 10 days	0%	20.0%
% sequences with protected intercourse on days 1-9 of phase	10.7%	27.3%

Users can intentionally have a sequence phase shorter then 10 days. However difficulty in counting and keeping track may also result in shorter sequences. It is useful therefore to examine difficulties participants had in keeping track of the days they could have unprotected intercourse. Participants used monthly calendars with special spaces to enter the information. We received a total of 721 calendars. Data entry was done in our Washington office, where a check was marked if it appeared that the woman did not mark the information correctly. Overall, the information was entered incorrectly in only 60 calendars (8.3%). However, it appears that incorrect markings in Peru were mostly the results of missed data. Users sometimes counted in their head, and neglected to mark the information in their calendar. In Guatemala, where the level of education and literacy was lower, but were participants tended to follow the marking directions more closely, only 3% of calendars had a marking mistakes.

Cycle 1

The guidelines instruct women in Cycle 1 to avoid unprotected intercourse from the 11th day of that cycle, until they get their next period. Therefore the length of the identified fertile period is variable, depending on cycle length. A total of 157 women used the *Guidelines* in Cycle 1. Of those 26 were admitted directly to this phase of the study; the others were admitted to the LAM or 10-day-rule phase, got their first postpartum menses and moved to Cycle 1. Some 134 of Cycle 1 users got their second postpartum menses and moved to the Cycles 2+ phase during the study period.

Cycle 1 is often longer then later cycles postpartum. This is confirmed in this study. While the shortest Cycle 1 in the study was 14 days, only 40.6% of women had a Cycle 1 shorter than 35 days. The mean length of Cycle 1 was 44.1 days and the median 37 days. The difference between mean and median is attributed to the very long tail of the distribution – six women had a Cycle 1 longer than 100 days (maximum 146 days).

While using the Guidelines in Cycle 1 seven women became pregnant – all used the method incorrectly (had unprotected intercourse after day 10), though one reported using withdrawal as backup. Only 19 women (12.4%) reported having unprotected intercourse at least once after day 10 of Cycle 1 (18.2% of Peruvians, but only 1.2% of Guatemalans). Of these seven became pregnant. More couples reported having protected intercourse after day 10 then in the ten-day-rule phase. Only 39.2% reported abstinence for the remainder of Cycle 1. This is understandable given the length of the period users avoid unprotected intercourse in Cycle 1.

Cycles 2+

After the second postpartum menses the *Guidelines* instruct users to avoid unprotected intercourse on days 8-24 (inclusive) of the cycle, until they have three consecutive cycles that are within the 26-32 day range. Some 139 participants entered this phase of the study. All moved form Cycle 1 when they got their second menses. They contributed between two and nine cycles (mean 3.6) for a total of 441 cycles.

On average Cycles 2+ were still longer then average non postpartum cycles, but they gradually became shorter. The mean cycle length in Cycle 2 was 34.5 days; in Cycle 3, 32.65 days, and in Cycle 4, 30.9 days.

Ten women became pregnant while using the *Guidelines* in Cycles 2+. Four of them had used the method correctly (two abstained and two used condoms on the fertile days). The other six had unprotected intercourse at least once on days 8-24 in the cycle that ended in pregnancy.

Participants reported having unprotected intercourse on the fertile days in only 26 cycles (0.8% of cycles from Guatemala; 13.4% of cycles from Peru). They reported abstinence on the fertile days in only 41.7% of cycles, and condom used in all other cycles.

Users can switch to the Standard Days Method after they have three consecutive cycles that are 26-32 days long, they. Since women left the study after nine months of *Guidelines* use, data from this pilot do not allow us to calculate the mean time postpartum it takes women to become eligible to use the Standard Days Method. However, of the 76 participants who contributed at least four cycles to the data post amenorrhea, 60 participants had three cycles within the 26-32 days range during the study period. For two thirds of them the third cycle within range was cycle 3 (13 women) or cycle 4 (27 women). Therefore most women would be eligible to use the Standard Days Method after four cycles postpartum.

9.2 Overall efficacy, continuation, and acceptability

Overall, 19 users became pregnant during the nine month study period:

- two in the 10th day-rule phase,
- seven in Cycle 1, and
- 10 in cycles 2+.

Only three of these pregnancies can be attributed to method failure, where the user correctly followed the *Guidelines* instructions. Nine of the pregnancies were reported in Guatemala and 10 in Peru.

Table 3 shows the typical use pregnancy rate for the first year of baby's life – or as close to a typical rate as possible given the study settings with intense follow up. The pregnancy rate was 8.6 (95% confidence interval 4.36-12.74). Short et al estimated that 50% of breastfeeding women having unprotected intercourse irrespective of when their menses returned would become pregnant by 12 months postpartum. A pregnancy rate of 8.6, then, indicates a significant protection from pregnancy for *Guidelines* users.

Table 7: Typical use life table pregnancy rates for the fertility awareness-based Family planning guidelines – First year postpartum

Months postpartum	Women exposed	Number of pregnancies	Pregnancy rate	95% confidence interval
1	174.0	0	0	0.00-0.00
2	174.0	0	0	0.00-0.00
3	175.0	1	0.57	-0.55-1.68
4	178.5	1	1.32	-0.44-2.67
5	180.5	2	2.22	0.04-4.36
6	180.5	0	2.22	0.04-4.36
7	180.0	1	2.77	0.35-5.13
8	177.5	2	3.86	1.02-6.63
9	166.0	3	5.60	2.16-8.91
10	156.5	4	8.01	3.89-11.96
11	146.0	1	8.64	4.36-12,74
12	127.5	0	8.64	4.36-12.74

Critics may say that women are not fertile in the first 2-3 postpartum months, even if they are not breastfeeding. Therefore a 1-year pregnancy rate should exclude these first months. We calculate an additional 1-year pregnancy rate, starting with month 4 postpartum and ending with month 15 postpartum. As table 4 shows, the typical use pregnancy rate for the 4-15 months postpartum year is 9.4 (95% confidence interval 4.67-13.93). This result also suggests a significant protection from pregnancy for *Guidelines* users.

Table 8: Typical use life table pregnancy rates for the fertility awareness-based Family planning guidelines – Months 4-15 postpartum

Months postpartum	Women exposed	Number of pregnancies	Pregnancy rate	95% confidence interval
4	178.5	1	0.56	-0.54-1.65
5	180.5	2	1.66	-0.22-3.51
6	180.5	0	1.66	-0.22-3.51
7	180.0	1	2.21	0.04-4.33
8	177.5	2	3.31	0.67-5.88
9	166.0	3	5.06	1.78-8.23
10	156.5	4	7.48	3.48-11.32
11	146.0	1	8.12	3.94-12.11
12	127.5	0	8.12	3.94-12.11
13	102.0	1	9.02	4.50-13.32
14	79.0	0	9.02	4.50-13.32
15	61.5	0	9.02	4.50-13.32

Most participants left the study at the end of 9 months of *Guidelines* use (44.0%) or because they had three consecutive months that were 26-32 days long (28.0%). There were 19 pregnancies, and five women who were lost to follow up. The *Guidelines* instruct women to return to their provider as soon as they menstruate, to receive counseling in the use of the next phase. In this study setting providers were instructed not to provide participants with Cycle 1 counseling if they returned after the first 10 days of the cycle. Two women left the study because they did not return to the provider soon enough. One additional woman left because of changed fertility intentions. Only 29 (14.4%) participants left the study because they or their partner did not like or trust the *Guidelines*.

When participants left the study for reasons other than pregnancy and lost to follow up, they were administered an exit interview, and asked how they felt about various aspects of *Guidelines* method use. Virtually all participants had something good to say about the method. The most frequent responses were that the *Guidelines* are natural and cause no side effect or health consequences (54.4%); they are effective in preventing pregnancy (29.2%); and they are easy to learn and use (23.6%).

X. Discussion And Conclusions

This pilot study demonstrated that the *Guidelines* are an effective and acceptable bridge between LAM and the Standard Days Method. We also have shown that clients find the transition between the phases of the *Guidelines* easy.

A weakness of the study is the relatively small sample size, and the short (9 months) duration of the study. Another weakness is the intense follow-up schedule and the requirement to complete a coital log, which were necessary for data collection but which might have increased correct use of the *Guidelines* and continuation rates.

Many questions remain unanswered, and need to be addressed before the *Guidelines* can be offered as part of regular service delivery on a large scale. First, while the pregnancy rate for the 10-day-rule phase was very low, the number of pregnancies in later cycles, was somewhat higher than expected (though results show that the *Guidelines* provide substantial protection from pregnancy in these cycles). Since the theoretical effectiveness of the *Guidelines* in these cycles is very high, we expect that the higher pregnancy rate reflects issues such as inappropriate understanding of a particular formula on the part of a user, or failing to remember to start using a newly learned formula, which can be addressed through better counseling in *Guidelines* use. A protocol for counseling should be developed and tested.

Second, in the study setting women who returned for counseling in later phases of the Guidelines after day 10 of Cycle 1 or after day 8 of Cycle 2 were exited from the study. A protocol for continued use of the *Guidelines* in cases when the woman returns late should be developed and tested.

Third, the *Guidelines* instruct women to use Cycle 2+ instructions until they have three consecutive cycles within the 26-32 days before they can switch to the Standard Days Method. Current protocol for Standard Days Method provision are less conservative, and allow providing the method to women if they had at least three cycles (4 menses) postpartum, and their last cycle was within the 26-32 day range. The demand for the Standard Days Method is high in places where it has been offered, and postponing start-up of SDM until the woman has three consecutive cycles within the 26-32 day range may results in many of these women becoming pregnant. However method provision can be more conservative if the *Guidelines* are available to address couples' need for a simple fertility awareness-based method of family planning until they are eligible to use the Standard Days Method. More research is needed to determine if the three consecutive cycles within range is the appropriate protocol, or if it can be somewhat relaxed without sacrificing efficacy. Similarly, some women may never re-establish cycle regularity postpartum. At which point will it be apparent that they may not be good candidates to use the Standard Days Method postpartum? What alternative can be offered them?

The *Guidelines* can address the need of women for simple accurate instructions for identifying the days they should avoid unprotect intercourse to prevent pregnancy

postpartum, after LAM is no longer effective, and until they are eligible to use the Standard Days Method. Further research is also needed about how best to offer the *Guidelines* in various setting. Are they best offered in family planning or reproductive health setting? in maternity hospitals? In well- baby programs? How should counseling be adapted for these various settings?

While the *Guidelines* are simple to teach, learn, and use, they require several provider-client interactions. This may pose a challenge for providers in some programs. For this pilot, a procedural decision was made to not attempt to teach all different formulae in one visit but instead teach each individual formula in separate visits as the woman moved from amenorrhea to the first and then subsequent cycles. Local program managers fully agreed that this would lead to better compliance. But the issue could be further tested if streamlining service delivery were considered critical.

In conclusion: the *Guidelines* for Postpartum Women can potentially meet an important unmet need for a particularly vulnerable population. The need to be further tested to confirm these preliminary results.

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